

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE PCT NATIONAL STAGE APPLICATION OF  
BETZ ET AL.

INTERNATIONAL APPLICATION NO: PCT/EP03/07346

FILED: 8 JULY 2003

U.S. APPLICATION NO: 10/520,570

35 USC §371 DATE: Herewith

FOR: LIQUID FORMULATIONS WITH HIGH CONCENTRATION OF  
HUMAN GROWTH HORMONE (HGH) COMPRISING GLYCINE

**MS: Missing Parts**

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

PETITION UNDER 37 CFR 1.47(a)

This Petition is being filed in response to the Patent and Trademark Office (PTO) Notification of Missing Requirements in the above-identified application. Specifically the Oath or Declaration of the Inventors is missing.

The named inventors in the above-described application are Michael Betz and John Stevens. John Stevens signed the enclosed declaration, however, Michael Betz refuses to sign the declaration. The last known address of the non-signing inventor is

Michael Betz  
Jagerstrasse 1  
8200 Schaffhausen  
Switzerland

In response to a request by Sandoz to sign the declaration in the above-described patent application which was already signed by his co-inventor, John Stevens, Mr. Betz faxed a reply letter stating that he refuses to sign the declaration. It is noted that Mr. Betz's letter is dated December 17, 2003, however, the date should be December 17, 2004, as evidenced by the date of the fax machine on top of the letter. In the letter, Mr. Betz states that he believes he is entitled to remuneration under Austrian law from his former employer, Biochemie/Sandoz, because he is a joint inventor of the subject matter claimed in the above-described patent application. In the last sentence of the letter, Mr. Betz states that he shall return the documents in a signed manner only after having reached an agreement. An English language translation

copy of Mr. Betz's letter is attached hereto, along with a copy of the original German language letter. .

In a letter dated May 17, 2005, Dr. Gasteiger, a Human Resource representative at Sandoz, informed Mr. Betz that he will receive remuneration provided that the prerequisites of Austrian Patent Law are fulfilled, for example, a patent is granted on the above-described patent application and the invention is used. An English language translation copy of Mr. Gasteiger's letter is attached hereto, along with a copy of the original German language letter. .

In response, Mr. Betz telephoned Dr. Gasteiger at Sandoz and requested a guarantee from Sandoz that he will receive remuneration for his invention. Dr. Gasteiger, or a colleague thereof, replied that Mr. Betz will receive remuneration provided the prerequisites of Austrian Patent Law with regard to remuneration are fulfilled.

Applicants submit that proof has been submitted that one of the inventors, Michael Betz, has been provided with a copy of the above-described application and refuses to sign the enclosed declaration. The requisite facts and background are supported by the accompanying letters attached hereto. Applicants further submit that a declaration has been submitted in response to a Notice of Missing Parts in which only one of the two named inventors has signed, as Michael Betz refuses to sign. For these reasons, Applicants request that this petition under 37 CFR 1.47(a) be granted and the application be forwarded for prosecution on the merits.

Enclosed is a Petition for a three-month extension of time.

The Commissioner is authorized to charge the \$130.00 surcharge fee (large entity status) and any further fee due under 37 CFR 1.17(h), or credit any overcharge, as a result of this Petition to Deposit Account No. 19-0134.

Respectfully submitted,

Novartis  
Corporate Intellectual Property  
One Health Plaza, Building 104  
East Hanover, NJ 07936-1080  
(862) 778-7945

  
\_\_\_\_\_  
John D. Thallemer  
Attorney for Applicants  
Reg. No. 34,940

Date: December/6 2005

12/23/2005 JFREY1 00000142 190134 10529370  
02 FD:1617 130.00 DA

Dr. Michael Betz, Jaegerstrasse 1, CH 8200 Schaffhausen

Bljana Colovic  
Novartis AG  
Corporate Intellectual Property  
4002 Basel

Schaffhausen, 17th December 2003 (2004)

**Patent applications: Liquid formulations with high concentrations of human growth hormone (HGH), containing 1,2-propylene glycol/ glycine / phenol**

Dear Frau Colovic,

Thank you for sending the declarations of assignment. It give me great pleasure to see that my inventions will be put to commercial use.

I have in my possession three sets of documents:

- One dated 6th August 2003, already signed by John Stevens, in respect of patent applications BP/G-32574P1; BP/G-32575P1 and BP/G-32576P1;
- one dated 10th December 2004, in respect of patent applications BP/G-32575A/BCK and BP/G-32576A/BCK (National Phase PCT/EP03/07349 and PCT/EP03/07346); and
- one dated 14th December 2004 in respect of patent application BP/G-32574BCK (National Phase PCT/EP03/07347).

In all the letters, I am requested to sign the said documents and thereby surrender to Sandoz AG all my rights in connection with these inventions.

In addition, there is my letter to Mr. Thomas Lehmeier of 1st September 2003, to which I have not yet received a reply.

In my letter, I pointed out *inter alia* §§ 7 to 17 of patent law, in which the Austrian legislation on the technical area of the patent relates expressly to the so-called service invention. When weighing up the interests between the employer and the employee inventor in the commercial evaluation of his invention, patent law operates on the principle that the result of work, in other words the invention of the employee, is not to be assigned for a fee to the employer, but a differential treatment regulation applies.

In any case, the employee is entitled to an appropriate special remuneration in accordance with § 8 para. 1 of patent law, because according to regulations the employee's salary does not count as compensation for inventive activity. The rights of the employee from the invention are unilaterally absolute in his favour according to § 17 of patent law, and remain in force even after termination of employment according to § 16 of patent law.

KOPIE

Dr. sc. Nat. Michael Betz

Corporate Intellectual Property

17. Dez. 2004

F.F. M.D. P.H. P.S. Copy

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8200 Schaffhausen  
SchweizTelefon: + 41 (0)52 - 640 2349  
[klatschmohn@gmx.ch](mailto:klatschmohn@gmx.ch)Dr. Michael Betz • Jägerstrasse 1 • CH 8200 SchaffhausenBiljana Colovic  
Novartis AG  
Corporate Intellectual Property  
4002 Basel

Schaffhausen, 17. Dezember 2003

Patentanmeldungen: Flüssige Formulierungen mit hohen Konzentrationen an humanem Wachstumshormon (HGH), enthaltend 1,2-Propylenglykol / Glycin / Phenol

Sehr geehrte Frau Colovic,

Besten Dank für die Zusendung der Abtretungserklärungen. Mit grosser Freude sehe ich die gewerbliche Nutzung meiner Erfindungen voranschreiten.

Vor mir liegen nun drei Dokumenten-Sets:

- Eines mit Schreiben vom 6. August 2003, bereits unterzeichnet von John Stevens, bezüglich der Patentanmeldungen BP/G-32574P1; BP/G-32575P1 und BP/G-32576P1;
- eines mit Schreiben vom 10. Dezember 2004 bezüglich der Patentanmeldungen BP/G-32575A/BCK und BP/G-32576A/BCK (Nationale Phase PCT/EP03/07349 und PCT/EP03/07346); sowie,
- eines mit Schreiben vom 14. Dezember 2004 bezüglich der Patentanmeldung BP/G-32574BCK (Nationale Phase PCT/EP03/07347).

In allen Schreiben werde ich gebeten, die genannten Dokumente zu unterzeichnen und damit alle meine Rechte im Zusammenhang mit diesen Erfindungen an die Sandoz AG abzutreten.

Desweiteren liegt vor mir mein Schreiben an Herrn Thomas Lehmeier vom 1. September 2003, das bisher unbeantwortet blieb.

In meinem Schreiben weise ich u.a. auf die §§ 7 bis 17 PatG hin, in denen der Österreichische Gesetzgeber im technischen Bereich des Patentes ausdrücklich für die sogenannte Diensterfindung Sorge trifft. Bei der Interessenabwägung zwischen der Dienstgeberseite und demjenigen des Dienstnehmererfinders an der kommerziellen Verwertung seiner Erfindung geht das Patentrecht davon aus, dass das Arbeitsergebnis, m.a.W. die Erfindung des Arbeitnehmers, nicht pauschal dem Dienstgeber zuzuordnen ist, sondern vielmehr eine differenzierte Regelung Platz greift.

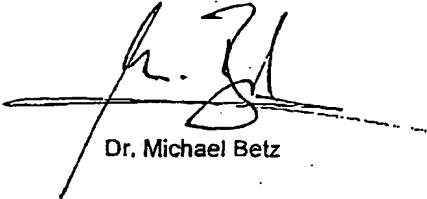
Jedenfalls gebührt dem Arbeitnehmer eine angemessene besondere Vergütung nach § 8 Abs. 1 PatG, weil der dem Dienstnehmer zustehende Arbeitslohn regelmässig nicht Entgelt für Erfindertätigkeit ist. Die Rechte des Dienstnehmers aus der Erfindung sind einseitig zwingend zu

seinen Gunsten gem. § 17 PatG und wirken selbst nach Auflösen des Dienstverhältnisses fort gem. § 16 PatG.

Ich möchte Sie nochmals bitten, mir die Sachlage aus Ihrer Sicht zu erläutern, v.a. im Hinblick auf eine angemessene Vergütung, da alle Ihre Schreiben in diesem Punkt sehr zurückhaltend formuliert sind (we do hereby sell and assign to Sandoz ... all our right, title and interest ...).

Sie werden verstehen, dass ich Ihnen die Dokumente erst nach einer Einigung unterzeichnet zukommen lassen werde.

Mit freundlichen Grüßen



Dr. Michael Betz



**SANDOZ**

Biochemiestr. 10, 6250 Kundl, Austria

Von Dr. Peter Gasteiger  
Human Resources  
Tel +43 (0)5338 200-3283  
Email peter.gasteiger  
@sandoz.com  
Datum 17. Mai 2005

Herrn  
Dr. Michael Betz  
Jägerstraße 1  
CH-8200 Schaffhausen

#### Patentanmeldung

Sehr geehrter Herr Dr. Betz,

wir sind von der Novartis Corporate Intellectual Property- Abteilung in Basel darüber in Kenntnis gesetzt worden, dass Sie die Dokumente zur Patentanmeldung für bestimmte flüssige Formulierungen mit hohen Konzentrationen an humanem Wachstumshormon bislang noch nicht unterschrieben haben.

An dieser Stelle möchten wir Sie nochmals höflich ersuchen, dies umgehend zu tun. Bezüglich des von Ihnen geltend gemachten Vergütungsanspruchs möchten wir nochmals auf die zwei hierfür notwendigen Voraussetzungen erinnern:

1. Vorliegen der Patentfähigkeit, festgestellt durch die Patenterteilung
2. eine kommerzielle Benutzungshandlung des (vormaligen) Dienstgebers.

Beides liegt gegenwärtig nicht vor, insbesondere ist der Zeitpunkt der kommerziellen Nutzung nicht abzusehen. Sind die Voraussetzungen gegeben, werden wir auch Ihre etwaigen Ansprüche auf Vergütung entsprechend den Bestimmungen des Patentgesetzes prüfen.

Weiters möchten wir Sie darauf hinweisen, dass Sandoz es sich vorbehält, entstehende Mehrkosten, die durch Ihre bisherige Weigerung, die oben erwähnten Dokumente zu unterfertigen, notfalls gerichtlich geltend zu machen. Sollte es durch die Nicht-

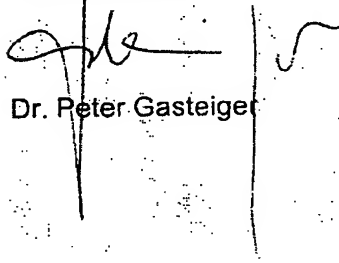


**SANDOZ**

Unterfertigung auch zu einem Verlust einer Patentanmeldung kommen, wird Sandoz Ihnen gegenüber Schadenersatzansprüche - nach entsprechender Prüfung - erheben. Wir gehen jedoch davon aus, dass es dazu nicht kommen wird und ersuchen Sie um entsprechende Kooperation. Herzlichen Dank!

Mit freundlichen Grüßen

Sandoz GmbH



Dr. Peter Gasteiger

I'd like to ask you again to explain the facts from your point of view, especially in respect of an appropriate remuneration, since all your correspondence on this point has been very recitent in this respect (we do hereby sell and assign to Sandoz... all our right, title and interest...).

You will understand that I shall let you have the signed documents only after we have reached an agreement.

Yours sincerely,

Dr. Michael Betz



Biochemiestr, 10, 6250 Kundl, Austria

From Dr. Peter Gasteiger  
Human Resources  
Tel +43 (0)5338 200 3283

Email peter.gasteiger  
@sandoz.com  
Date 17th May 2005

Dr. Michael Betz  
Jägerstraße 1  
CH-8200 Schaffhausen

### **Patent application**

Dear Dr. Betz,

We have been told by the Novartis Corporate Intellectual Property Department in Basel that you have not yet signed the documents for filing a patent application for certain liquid formulations with high concentrations of human growth hormone.

At this point, we would politely request you to do so by return. Regarding the claim for reimbursement which you have put forward, we would like to remind you of the two conditions for this:

1. Existence of patentability, established by grant of patent
2. a commercial act of use by the (former) employer.

Neither exists at present; in particular, we do not envisage when commercialisation will take place. When the conditions apply, we will examine any claims you may have for reimbursement in accordance with the provisions of patent law.

Furthermore, we would point out that Sandoz reserves the right to legally enforce if necessary any additional costs incurred by your refusal to sign the afore-mentioned documents. If the non-signing should also result in the loss of a patent application, Sandoz will present you with a statement of claim for damages - after appropriate verification. We presume that it will not come to this, and request your co-operation. Thank you!

Yours sincerely

Sandoz GmbH

Dr. Peter Gasteiger



## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

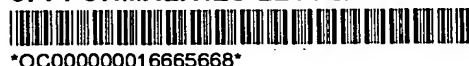
U.S. APPLICATION NUMBER NO. 10/520,570	FIRST NAMED APPLICANT Michael Betz	ATTY. DOCKET NO. BP/G-32576A/BCK
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001095  
NOVARTIS  
CORPORATE INTELLECTUAL PROPERTY  
ONE HEALTH PLAZA 104/3  
EAST HANOVER, NJ 07936-1080

JDT

INTERNATIONAL APPLICATION NO. PCT/EP03/07346	
IA. FILING DATE 07/08/2003	PRIORITY DATE 07/09/2002

CONFIRMATION NO. 5942  
371 FORMALITIES LETTER



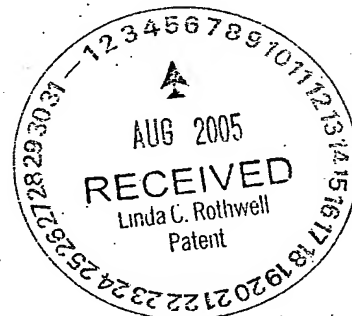
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Date Mailed: 08/02/2005

### NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Copy of the International Application filed on 01/07/2005
- Copy of the International Search Report filed on 01/07/2005
- Copy of IPE Report filed on 01/07/2005
- Preliminary Amendments filed on 01/07/2005
- Information Disclosure Statements filed on 01/07/2005
- Oath or Declaration filed on 01/07/2005
- U.S. Basic National Fees filed on 01/07/2005
- Priority Documents filed on 01/07/2005
- Power of Attorney filed on 01/07/2005



The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date. The current oath or declaration does not comply with 37 CFR 1.497(a) and (b) in that it:
  - is not executed in accordance with either 37 CFR 1.66 or 37 CFR 1.68.
- \$130 Surcharge for providing the oath or declaration later than 30 months from the priority date (37 CFR 1.492(e)) is required.

## SUMMARY OF FEES DUE:

Total additional fees required for this application is \$130 for a Large Entity:

DOCKETED FOR: Oct 2, 2005

- **\$130** Late oath or declaration Surcharge.

**ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.**

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

*A copy of this notice **MUST** be returned with the response.*

PATRICIA A BOOKER

Telephone: (703) 308-9140 EXT 204

**PART 1 - ATTORNEY/APPLICANT COPY**

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/520,570	PCT/EP03/07346	BP/G-32576A/BCK

FORM PCT/DO/EO/905 (371 Formalities Notice)

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